K974845

DEC 8 1998

510(k) SUMMARY INFORMATION

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

A. Submitter's Information:

Submitter's Name:	Bion Diagnostic Sciences, Inc.
Address:	12277 134th Court NE, Redmond WA 98052
Contact Person:	Alicia Moffat
Contact Person's Phone:	(425)814-1502
Contact Person's Fax:	(425)814-1520
Date of Preparation:	September 11, 1998

B. Device Name:

Trade Name:	BTA *stat* Test
Common/Usual Name:	BTA *stat* Test
Classification Name:	Tumor Associated Antigen Immunological Test System

C. Predicate Device Name:

Trade Name:	BTA *stat* Test K964151

Bion Diagnostic Sciences claims substantial equivalence to the above mentioned test. The new 510(k) is for the addition of an indication for prescription home use.

D. Device Description:

The BTA *stat* test for bladder tumor associated antigen is an immunochromatographic assay utilizing monoclonal antibodies to specifically detect the presence of bladder tumor associated antigen in urine. Patient urine is added to the sample well and allowed to react with a colloidal gold-conjugated antibody. If the antigen is present in the sample, an antigen conjugate complex is formed and a line in the patient (P) test zone appears.

E. Intended Use:

The BTA *stat* test is an *in vitro* diagnostic immunoassay indicated for the qualitative detection of bladder tumor associated antigen in urine of persons diagnosed with bladder cancer.

F. Indications for Use:

The BTA *stat* test is indicated for prescription home use as an aid in the management of bladder cancer patients in conjunction with cystoscopy.

G. Substantial Equivalence and Technological Characteristics Summary:

The BTA *stat* test is a lateral flow assay which detects bladder tumor associated antigen using antigen-specific antibodies. This 510(k) is only for the expanded indication of prescription home use; there are no product changes. Two studies were conducted to demonstrate that lay users could read the test instructions and perform the test acceptably well compared to laboratorians. In the first study, the accuracy and repeatability of BTA *stat* test results generated by laboratorians and professional lay-persons at three sites were compared and no significant differences in these test performance characteristics were observed between the groups. The second study evaluated the accuracy demonstrated by persons with a previous diagnosis of bladder cancer in performance of the BTA *stat* test and tested the subjects's ability to comprehend the information in the new "Instructions for Home Use" product labeling. The results indicated that the intended home user population can perform the test at the same level of accuracy observed in laboratory professionals in the first study and that the labeling is easily understood by bladder cancer patients. Several labeling changes were prompted by this study, also.

In conclusion, the BTA *stat* test when used by lay persons is substantially equivalent to the predicate device referenced in this submission (the same test) when used by laboratory professionals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 8 1998

Ms. Alicia Moffat
Regulatory affairs Manager
Bion Diagnostic Sciences, Inc.
12277 134th Ct. N.E.
Redmond, Washington 98052

Re: K974845
Trade Name: BTA *stat®* Test
Regulatory Class: II
Product Code: MMW
Dated: December 17, 1997
Received: December 18, 1998

Dear Ms. Moffat:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K974845

Device Name: BTA *stat*® Test

Indications for Use:

The BTA *stat* test is indicated for use as an aid in the management of bladder cancer patients in conjunction with cystoscopy. This 510(k) is to expand the same indication to prescription home use of the product. The original 510(k) was K964151.

Peter E Mahan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974845

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use ✓ Over-the-Counter Use _____
(Per 21 CFR 801.109)

Prescription Home Use ✓

(Optional Format 1/2/96)